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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,503	12/31/2003	Victor I. Chomenky	1004.010	1817

7590 05/25/2005
Craig Gregersen
P.O. Box 386353
Bloomington, MN 55438

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,503

Applicant(s)

CHORNENKY ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/17/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on March 17, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "configured to be carried by an individual."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, does not disclose that the system of Applicants' invention is "configured to be carried by an individual."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US 6,070,761) in view of MacPherson et al. (US 5,704,223) and Eibl et al. (US 5,776,452).

Bloom et al. disclose an automated and portable medication management system 300 for intravenous administration of drugs (Figure 3, Figure 7, col. 1, lines 17-20 and lines 59-67, col. 2, lines 6-14 and lines 27-60, and col. 5, lines 53-57) with one or more drug vials 85 in a cassette or library of medication 77 and a bag 89 with diluent and additives for reconstitution of drug in vials 85 (col. 13, lines 35-53, col. 14, lines 7-15, Figures 5A and 5B). Further, Bloom et al. disclose system 300 to contain an infusion pump 88 with valves 112 to enable fluid communication between the source of diluent or bag 89, the drug vials 85 (col. 13, lines 54-60 and col. 16, lines 61-64, Figure 7 and Figure 8) and the patient. Bloom et al. also disclose a microprocessor based control unit 304 in system 300 which controls drug reconstitution and/or dilution and also controls the delivery of medication to the patient (Figure 16, Figure 19, col. 7, lines 36-39 and lines 57-62). The system 300 of Bloom et al. also has a battery 105 as an alternative power source for mobile or "portable" use (col. 15, lines 40-42 and col. 20, lines 48-51).

Bloom et al. disclose all elements of the claimed invention except for a battery-operated micro cooler for keeping the medication library at reduced temperatures for long-term preservation of drugs in vials 85 and drugs such as thrombolytic agents.

MacPherson et al. teach a battery-operated thermoelectric cooling bag for keeping drugs in a controlled-temperature environment (0 degrees to 30 degrees Celsius) for their preservation (Fig. 1, col. 1, lines 11-37 and col. 2, lines 17-67).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a thermoelectric cooling bag in the system 300 of Bloom et al. for storage of drug vials 85, as taught by MacPherson et al., to preserve the potency of the drugs.

Further, thrombolytic medications are well known as evidenced by Eibl et al. (see col. 1, lines 28-35, col. 2, lines 66-67, col. 3, lines 1-21 and col. 4, lines 42-47). It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to have provided a thrombolytic agent in the system of the combination of Bloom et al. and MacPherson et al. because it was known in the art to use thrombolytic agents for treatment of a patient suffering from thromboembolism, a well-known cause of heart attacks.

The introductory statement and all other functional statements of intended use have been carefully considered but are deemed not to impose any structure on the claims distinguishable over the Bloom et al. – MacPherson et al. system which is capable of administering thrombolytic therapy as claimed.

Regarding claim 2, Bloom et al. further disclose that control unit 304 is connected to a communications interface 320 for communication or programming by networks or entities (Figure 3, col. 7, lines 41-44 and lines 63-67, col. 8, lines 28-35, col. 21, lines 46-50, col. 22, lines 7-10 and Figure 16).

Regarding claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have maintained the temperature controlled environment below 5 degrees Celsius, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 5, system 300 is programmed by a physician to prescribe medication and a clinician to administer medication (col. 12, lines 30-46 and col. 13, lines 54-56).

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on March 17, 2005 have been fully considered but are not persuasive for the following reasons. The word "portable" means "capable of being carried or moved about." The prior art system meets both these definitions in that it is capable of being carried or moved about.

Applicants' arguments are directed to intended use of a device. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

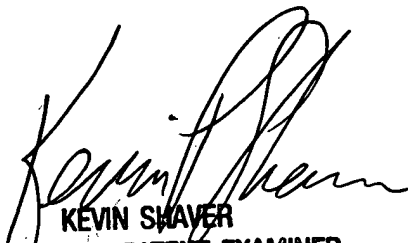
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Annabella Ramona*
May 20, 2005


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700